DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 10, 2014

11 Health and Technologies LLC
% EJ Smith
Consultant
Smith Associates
1468 Harwell Avenue
Crofton, MD 21114

Re: K140938
Trade/Device Name: Ostom-i™ Alert
Regulation Number: 21 CFR§ 876.5900
Regulation Name: Ostomy Bag Accessory
Regulatory Class: I
Product Code: EXB, EZQ, EZS
Dated: September 2, 2014
Received: September 2, 2014

Dear EJ Smith,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140938

Device Name
OSTOM-i™ Alert

Indications for Use *(Describe)*

The OSTOM-i™ Alert is intended to be used as an accessory to any ostomy bag by monitoring the filling of the bag which information is sent via Bluetooth to a tablet computer to warn healthcare personnel when a patient's bag is close to being full. The Tablet computer automatically captures the data as to the volume and timing of output for each patient.

The OSTOM-i™ Alert is indicated for all patient populations.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140938

Device Name
OSTOM-i™ Alert

Indications for Use *(Describe)*

The sensor-based OSTOM-i™ Alert attaches to any ostomy bag and is able to send messages via Bluetooth to a mobile app to warn patient when ostomy bag is close to being full. The sensor-based OSTOM-i™ Alert is intended to be used by the patient outside of the hospital environment.

The OSTOM-i™ Alert is indicated for all patient populations.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary
807.92(c)

SPONSOR **807.92(a)(1)**

Company Name: 11 Health Technologies
Company Address Kinetic Business Centre
Theobald Street
Borehamwood WD6 4PJ
United Kingdom

Telephone: +44 (0) 20 8387 4000

Contact Person: Michael Seres

Summary Preparation Date: October 9, 2014

DEVICE NAME **807.92(a)(2)**

Trade Name: Ostom-i
Common/Usual Name: Ostomy Bag/Pouch
Classification Name: Collector, Ostomy
Regulation Number**:** 21 CFR 876.5900
Regulation Name: Ostomy Pouch and Accessories
Product Code: EXB, EZQ, EZS
Device Class: Class I

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

K Number	Product Name	Manufacturer
K813269	Two Piece Ostomy System	Hollister, Inc

DEVICE DESCRIPTION **807.92(a)(4)**

The sensor-based OSTOM-i™ Alert attaches to any ostomy bag and is able to send messages via Bluetooth to a mobile app to warn the health care provider when their patients' bags are close to being full, or to the patient in the post-hospital setting.

The flex sensor changes its resistance according to curvature and converts resistance into mls, thereby detecting the progressive filling of the bag. This information is relayed to the tablet generating an additional report on bag status versus the visual one now available.

DEVICE INDICATIONS FOR USE **807.92(a)(5)**

Prescription Use Only

The OSTOM-i™ Alert is intended to be used as an accessory to any ostomy bag by monitoring the filling of the bag which information is sent via Bluetooth to a tablet computer to warn healthcare personnel when a patient's bag is close to being full. The Tablet computer automatically captures the data as to the volume and timing of output for each patient.

The OSTOM-i™ Alert is indicated for all patient populations.

OTC

The sensor-based OSTOM-i™ Alert attaches to any ostomy bag and is able to send messages via Bluetooth to a mobile app to warn patient when ostomy bag is close to being full. The sensor-based OSTOM-i™ Alert is intended to be used by the patient outside of the hospital environment.

The OSTOM-i™ Alert is indicated for all patient populations.

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

Parameters	11 Health and Technologies, LLC	Hollister, Inc.
K number		K813269
Regulatory Classification	Class I Exempt 21 CFR 876.5900	Class I Exempt 21 CFR 876.5900
Product Code	EXB	EXB
Indications for Use	The OSTOM-i™ Alert is intended to be used as an accessory to any ostomy bag by monitoring the filling of the bag which information is sent via Bluetooth to a tablet computer to warn healthcare personnel when a patient's bag is close to being full. The Tablet computer automatically captures the data as to the volume and timing of output for each patient. The sensor-based OSTOM-i™ Alert attaches to any ostomy bag and is able to send messages via Bluetooth to a mobile app to warn patient when ostomy bag is close to being	An ostomy pouch and accessories is a device that consists of a bag that is attached to the patient's skin by an adhesive material and that is intended for use as a receptacle for collection of fecal material or urine following an ileostomy, colostomy, or ureterostomy (a surgically created opening of the small intestine, large intestine, or the ureter on the surface of the body).

	full. The sensor-based OSTOM-i™ Alert is intended to be used by the patient outside of the hospital environment. The OSTOM-i™ Alert is indicated for all patient populations.	
Use environment	Hospital and home use	Hospital and home use
Patient Population	Patients using Ostomy Bags	Patients using Ostomy Bags
Disposable	Single patient use	Single patent use
Device Design: Collection	Ostomy bag with portable level sensor attached	Ostomy bag
Device Design: Fill Status	Visual and alert via sensor detection which sends fill alert via Bluetooth to a dedicated device, a tablet computer	visual

NON-CLINICAL PERFORMANCE DATA **807.92(b)(1)**

Performance Testing-Usability and Label Comprehension Study by Intended User

The testing for ease of use and label comprehension of the 11 Health Ostom-i™ Hospital App with the Ostom-i™ Alert Sensor by nurses who would use this in a hospital setting was the object of this usability study. Nurses are the primary caregivers in the maintenance of ostomy bags in the hospital setting.

The usability factors included the ability of the healthcare professional to read and understand the Hospital App Instructions for Use, interface with Tablet by inputting patient information, attach the sensor to the ostomy bag and after enabling the battery, pair the sensor to the Tablet. An alert was simulated by curving the bag to the filling of the bag thereby creating the alarm condition.

PERFORMANCE TESTING

The following performance tests were conducted:

- Patient Usability Testing:
  - Patients standing
  - Patients lying down

  - Patients sitting down with ostomy bag folded in half
  - Device dropped in water
  - Water splashed on device
  - Patient climbing stairs
  - Patient rolling over 360 degrees
  - Patient bending over
  - Patient driving
- Label comprehension study
- Usability study by ICU registered nurses
- Biocompatibility testing in accordance with ISO 10993
- Electromagnetic compatibility
- Wireless coexistence

CONCLUSION **807.92(b)(3)**

The primary intended use of an ostomy bag is a collection device. The OSTOM-i™ Alert is an accessory to the ostomy bag which does not alter an ostomy bag's function as a collection device but rather adds a graphic fill status and alert of critical fill level to the healthcare provider via BlueTooth to a tablet computer, which is a technological improvement over intermittent visualization. In addition, information concerning amount of out- put and time of output is available for clinical purposes, if clinically indicated. The OSTOM-i™ Alert raises no new issues of safety and effectiveness for its intended use, but is a technological advance of simple visualization of ostomy fill and is substantially equivalent to the predicate device.